PATENT COOPERATION TREATY

PCT

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P. AURI.01/WO	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/BE2004/000011	International filing date *(day/month/year)* 20.01.2004	Priority date *(day/month/year)* 20.01.2003
International Patent Classification (IPC) or both national classification and IPC A61K7/48		
Applicant AURIGA INTERNATIONAL S.A. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
10.09.2004	06.05.2005
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Yon, J-M Telephone No. +49 89 2399-7535

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/BE2004/000011

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-10 as originally filed

Claims, Numbers

1-17 filed with telefax on 13.09.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-11
	No:	Claims	
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-11
Industrial applicability (IA)	Yes:	Claims	1-11
	No:	Claims	

2. Citations and explanations

see separate sheet

Reference is made to the following document from the International Search Report :

D1: DATABASE WPI Section Ch, Week 199402 Derwent Publications Ltd., London, GB; Class B05, AN 1994-012183 XP002244372 & JP 05 320039 A (TAIYO KAGAKU KK) 3 December 1993 (1993-12-03)

The documents **D5** and **D6** were not cited in the international search report. Copies of the documents are appended hereto.

D5 : DE 4302132 (GOLDWELL) 13 January 1994 (13.01.1994)
D6 : US 5540934 (TOUITOU) 30 July 1996 (30.07.1996)

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

In the light of the cited documents, it appears that independent claim 1 (use) satisfies the criteria set forth in Articles 33(2) and (3) PCT.

However, independent claim 11 (composition) does not satisfy the criteria set forth in Article 33(3) PCT for the following reasons :

The technical problem the Applicant seeks to solve is to provide a stable vitamin K1-containing composition as well as in improved activity, via an enhanced penetration ; moreover, the Applicant is aiming at a composition which does not present the yellow colour as well as not being sensitive to light or UV-radiation.

The solution provided by the Applicant consists in the use of vitamin K1 oxide with phospholipids and ethoxy diglycol.

As disclosed in document **D1**, a cosmetic composition comprising vitamin K1 oxide is already

known.

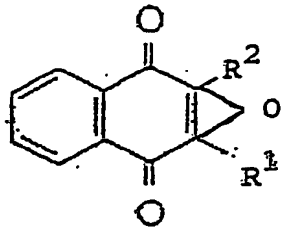
The present application differs therefrom in that it comprises phospholipids and ethoxy diglycol.

Said two components are well known from the skilled man as being the constituents for preparing vesicles such as liposomes or nanosomes, themselves also well known for enhancing the penetration of various actives into the skin, thereby improving the activity of the product (see also **D5** and **D6**). Therefore, said effect was fully expected and can not lead to an inventive step.

If the Applicant considers that because of the incorporation of the phospholipids and the ethoxy diglycol, the compositions according to the present application lead to a particular advantage or an unexpected effect, he is invited to provide evidence through comparative tests.

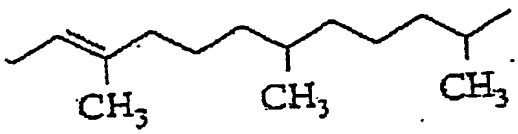
CLAIMS

1. Use of a composition comprising an adequate pharmaceutical or cosmetic carrier (or diluent) and a sufficient amount of a compound formula I



wherein R1 is an alkyl group and wherein R2 is H or an alkyl group for the manufacture of a medicament in the treatment and the prevention of mammal dermatological lesions.

2. The use of claim 1, wherein R1 is an alkyl chain of formula II



wherein R2 is a methyl.

3. The use of claim 1 or 2, wherein the lesion to select from the group consisting of bruises, vascular disorder on the skin, spider veins, varicoses, blotches on the face, purpura on the face, body or legs, irritation following use of chemical peel, Shambourg's disease or a mixture thereof.

4. The use of claim 1 or 3, wherein the compound is present in nano-sized lipidic particles, comprised between about 50 and about 400 nanometers in diameter.

5. The use of claim 4, wherein the nano-sized lipidic particles have a diameter of about 180 nanometer.

6. The use of claim 4 or 5, wherein the nano-sized lipidic particles are made of phospholipid layers.

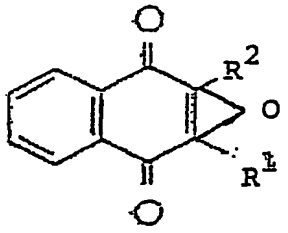
7. The use according any of the preceding claims, wherein the composition is a cosmetic composition comprising a sufficient amount of the compound and an adequate cosmetic carrier.

8. The use of claim 7, wherein the sufficient amount of the compound is comprised between about 0.5% wt and about 10% wt of the composition.

9. The use of claim 7 or 8, wherein the cosmetic composition is in the form of a cream, a gel, a lotion or a liquid.

10. The use according to any of the preceding claims 7 to 9, wherein the composition further comprised other vitamins, preferably vitamins selected from the group consisting of vitamin A, vitamin C, vitamin E or a mixture thereof.

11. A cosmetic composition which comprises an adequate cosmetic carrier, phospholipids, ethoxy diglycol and a compound of formula I

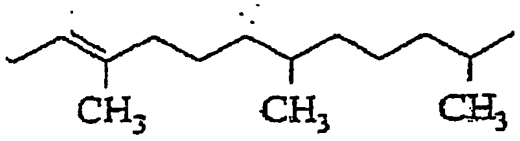


, wherein R1 is an alkyl group and wherein R2 is H or an alkyl group, for the treatment and/or the prevention of mammal dermatological lesions, selected from the group consisting of bruises, vascular disorder on the skin, spider veins, varicooses, blotches on the face, purpura on

the face, body or legs, irritation following use of chemical peel, Shambourg's disease or a mixture thereof.

12. The cosmetic composition according to claim 11, which is in the form of a cream or a gel.

13. The cosmetic composition of claim 11 or 12, wherein the compound of formula I, R1 is a alkyl chain of formula II



wherein R2 is a methyl.

14. The cosmetic composition according to any of the claims 11 to 13, wherein the compound is present in nano-sized lipidic particles, comprised between about 50 and about 400 nanometers in diameter.

15. The cosmetic composition according to claim 14, wherein the compound is present in nano-sized lipidic particles of about 180 nanometer in diameter.

16. The composition of claim 14 or 15, wherein the nano-sized lipidic particles are made of a phospholipid layer.

17. The cosmetic composition according to the claims 11 to 16, wherein the compound is present in a percentage in the composition comprised between about 0.5% wt to about 10% wt of the composition.